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My Health Record Software Vendor Guide to the Connection Process

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1 Welcome to the My Health Record system

Thank you for your interest in developing software to access the My Health Record system.

This document describes the steps required in preparing a Clinical Information System (CIS) or software used by a Contracted Service Provider (CSP) for connection to the My Health Record system (previously known as PCEHR or Personally Controlled Electronic Health Record).

On 1 July 2015 the approach for conformance and compliance of systems transacting with the My Health Record system, moved to an industry-enabled model. A self-declaration approach now applies, where a vendor declares that their product complies with the required My Health Record conformance profiles and specifications.

This document provides an overview of the process required to connect your software to the My Health Record system production environment. Table 1 describes the type of access available, based on the access channel used to connect to the My Health Record system.

Table 1 – Access channel matrix

Access channel	View access	Upload access
B2B Gateway	Supported	Supported
B2B CIS to NPP Service	Supported	Not Supported

For further assistance in navigating the registration process, please consult the Australian Digital Health Agency (the Agency) website at: www.digitalhealth.gov.au.

1.1 The welcome pack

The welcome pack contains:

- Guide to the My Health Record system connection process (this document)
- Software vendor product details form
- Conformance vendor declaration form
- Instructions for completing the conformance declaration form
- My Health Record system vendor contacts list.

If you have feedback on this kit, please email myhealthrecord.operations@digitalhealth.gov.au with the subject line: *My Health Record Welcome Pack*.

1.2 Moving to the next stage

When completed, return the Software Vendor Product Details Form and the Application to Request a National Authentication Service for Health (NASH) Public Key Infrastructure (PKI) Test Certificate to the Services Australia Online Technical Support (OTS): otsliaison@servicesaustralia.gov.au

2 Pre-requisites for access to the My Health Record system

Depending on the type of software you are developing and access channel you are going to use, the pre-requisites in Table 2 will apply.

Table 2 - Pre-requisites matrix

Access channel	Type of software	
	CIS	CSP
B2B Gateway (View and upload access)	<ul style="list-style-type: none">• Connection to the HI Service• HPI-I and HPI-O• NASH PKI test certificates	<ul style="list-style-type: none">• Connection to the HI Service• HPI-I• NASH PKI test certificates of CSP organisation
B2B CIS to NPP Service (View access only)	<ul style="list-style-type: none">• HPI-O and HPI-I• NASH PKI test certificate	Not Supported

2.1 Healthcare Identifiers Service

The Australian state and territory governments have developed a national HI Service, which uniquely identifies healthcare providers and individuals who seek to be involved in healthcare in Australia. Services Australia is the operator of the HI Service. The HI Service gives individuals and healthcare providers confidence that the right health information is associated with the right individual at the point of care.

To connect to the My Health Record system, a CIS must be able to verify data through the HI Service. This ability, whether it exists within the software itself, or is provided through another integrated system, is a pre-requisite for connection to the My Health Record system. It is important that you understand how your product will interact and connect to the HI Service as part of interacting with the My Health Record system.

For more information on the HI Service, including information on developing software to connect to the HI Service, go to the Services Australia website for health professionals and developers (software vendors):

<http://www.medicareaustralia.gov.au/provider/vendors/healthcare-identifiers-developers/index.jsp>

Note: The HI Service is not required for clinical software connecting to My Health Record using the B2B CIS to NPP Service.

2.2 Test HPI-I, HPI-O or CSP NASH PKI certificates

To gain access to the My Health Record Software Vendor Test (SVT) environment, you must obtain the following test certificates and healthcare identifiers:

- NASH PKI certificate
- HPI-O
- HPI-I

The type of test certificates and healthcare identifiers required depend on your software type and the access channel you are using. Refer to Table 2 for more information.

NASH PKI test certificates will allow you to develop and test the workflow of your product by facilitating:

- authentication to the test environment for the My Health Record system (healthcare providers utilise NASH PKI organisation certificates to authenticate in the production environment); and
- testing the sending and receiving of secure messages.

The test certificates cannot be used in production and cannot be linked for use with the HI Service or any other online program. Software vendors are bound by the terms and conditions of the licence agreed to when applying for a NASH PKI test kit.

The NASH PKI test kit contains the following certificates:

- an active test NASH PKI organisation certificate for Healthcare Provider Organisations for two test organisations
- a revoked test NASH PKI certificate for Healthcare Provider Organisations for a test organisation, if requested, and
- an active test NASH PKI certificate for Supporting Organisations for a test organisation, if requested.

Test organisation names will vary in different test kits. Any healthcare identifiers embedded in the certificates are test healthcare identifiers only. Test certificates are valid for two years.

To receive your test certificates, complete the following form and email to OTSLiaison@servicesaustralia.gov.au:

Application to request a National Authentication Service for Health Public Key Infrastructure Test Certificate kit:

<https://developer.digitalhealth.gov.au/sites/default/files/application-request-nash-pki-test-certificate.pdf>

The form contains the terms and conditions to obtain a test certificate and related software and materials.

Note: A processing time of approximately two weeks is required.

3 Testing

There are two types of testing required to validate your software product for connection to the My Health Record system. These are:

- Conformance and compliance testing. Your own internal self-assessment testing in preparation for Conformance, Compliance and Declaration (CCD); and
- Notice of Connection (NOC) testing. Testing your software using test cases and test data, provided by the System Operator, and observed by the National Infrastructure Operator (NIO).

All software products must successfully pass these testing requirements before gaining access to the My Health Record production system.

3.1 Conformance and compliance testing

Conformance and compliance testing supports the safe and secure implementation and use of the My Health Record system as part of the CCD process. The CCD process requires that your software conforms to all applicable conformance profiles and the specifications they reference, and the conformance requirements for My Health Record Connecting Systems (Specifications), prior to your software being granted connection to the My Health Record system. Furthermore, you are required to maintain compliance following connection of your product to the production environment.

All technical specifications are available on the Agency website:

<https://www.digitalhealth.gov.au/implementation-resources>

You verify conformance of your software product by conducting self-assessment testing using the conformance test specifications that are also available from the Agency website, in conjunction with the Clinical Package Validator tool. You are required to retain evidence of the tests performed during self-assessment testing.

3.2 My Health Record Notice of Connection (NOC)

All software products need to pass NOC testing. NOC testing confirms that your software product performs according to the specified standards and conformance points defined in the technical and logical service specification documents. These documents are referenced within each implementation guide available on the Agency website:

<https://www.digitalhealth.gov.au/implementation-resources>

Once you have submitted the *Software Vendor Product Details Form* to OTS, NIO will send you a test plan, which includes the services nominated for use during the NOC process. NIO will observe NOC testing and when completed successfully, they will issue you with a *My Health Record Declaration of Notice of Connection* for the specific version of your product that has been tested.

3.2.1 My Health Record Conformance Vendor Declaration Form

Upon completion of both NOC and conformance testing, you must complete the Conformance Vendor Declaration Form (for instructions, see: Instructions for completing the Conformance Vendor Declaration Form). By completing the Conformance Vendor Declaration Form, you are declaring conformance against the conformance profiles and specifications.

3.2.2 Vendor Deed Poll

Attached to the *My Health Record Conformance Vendor Declaration Form* is a *Vendor Deed Poll* that outlines several operational obligations to which you must agree when connecting a software product to the My Health Record system. The deed poll requires a signature from an authorised delegate of your organisation. The signature on the deed poll must be witnessed.

The System Operator has a responsibility to perform regular quality assurance analysis of the data and transactions submitted by products that connect to the My Health Record system (Operative Provision 9 in deed poll). If required, your organisation may be requested to assist with any product-specific analysis undertaken. The System Operator will keep your organisation informed of any findings related to your product(s).

Please email the completed *Conformance Vendor Declaration Form* to:
myhealthrecord.operations@digitalhealth.gov.au

3.3 CIS or CSP software connecting via the B2B Gateway

If you are developing a CIS product for connection to the My Health Record system via the B2B Gateway, please also consider developing and testing your product for use by a CSP. To be eligible for use by a CSP, CIS software requires a change to the transaction header. One option may be to control the CSP functionality through the product's configuration management.

For software to gain approval for use as a CIS or CSP product, it must pass a full set of NOC and CCD, CIS or CSP test cases. If a product is already approved for connection as one of these system types and additional approval is being sought (for example, change to support both CIS and CSP), then supplementary test cases per service must be passed.

Specification references for CSP testing are available from:

<https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/pcehr-b2b-gateway-services>

The key Logical Service Specifications (LSS) and Technical Service Specifications (TSS) for the B2B Gateway are:

- Document Exchange Service LSS/TSS
- Record Access Service LSS/TSS
- View Service LSS/TSS
- Registration Service LSS/TSS.

3.4 CIS software connecting via the B2B CIS to NPP Service

Specification references for CIS software connecting via the B2B CIS to NPP Service are available from:

<https://developer.digitalhealth.gov.au/specifications/national-infrastructure/ep-2876-2019>

The key service specifications for the B2B CIS to NPP Service are:

- CIS to NPP Technical Service Specification
- National Provider Portal (NPP) CIS to NPP Implementation Guide.

3.5 Product authorisation

The System Operator will authorise a specific version of your software product to access the My Health Record system when the following occur:

- your software product is approved for connection to the HI system, with testing observed by Services Australia
- your software product passes your internal conformance testing
- your software product passes the relevant connectivity tests (NOC)
- you complete the *Conformance Vendor Declaration Form*.

3.6 Notification of environment availability

OTS will issue email notifications when the SVT or the production environments experience an outage. To receive these messages, please keep your contact details current by emailing myhealthrecord.operations@digitalhealth.gov.au with the subject line: Vendor contact details.

The SVT environment is supported during business hours (8:30am to 5:00pm) Monday to Friday, Eastern Standard Time, excluding ACT public holidays.

4 Vendor conformance process

4.1 Vendor conformance process overview

Figure 1 summarises the steps necessary to test your product prior to connecting to the My Health Record system. Section 4.2 describes these steps in more detail.

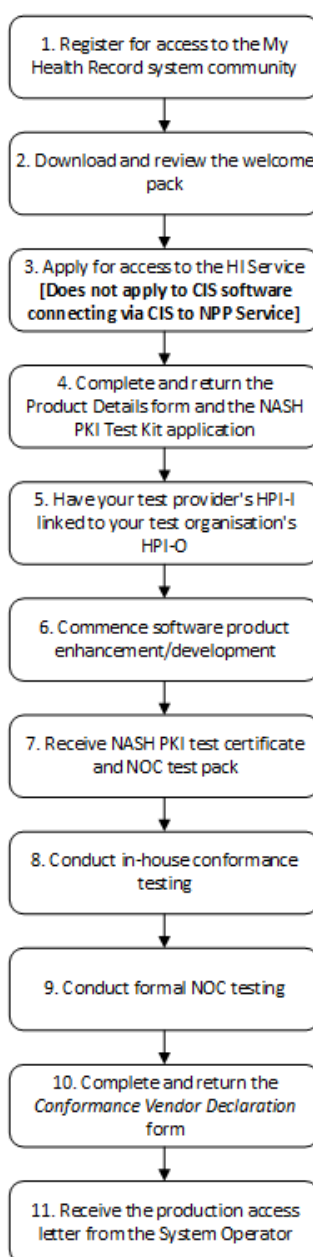


Figure 1 - Vendor conformance process

4.2 Vendor conformance process description

Table 3 provides a description of vendor actions required for each step of the vendor conformance process. The step numbers correlate to the numbers within the process flow described in Figure 1.

Note: The My Health Record system was previously known as the Personally Controlled Electronic Health Record (PCEHR) and there may still be references to PCEHR in the various conformance and specifications documents.

Table 3 - Required vendor actions

Step	Stage	Vendor action	Result
1.	Register to join the My Health Record Developer Community	<ul style="list-style-type: none"> • Create an account at: https://developer.digitalhealth.gov.au/user/register • Enter your personal information • Accept the terms of use • Complete the registration process • Read the latest versions of recommended documents presented after registration: <ul style="list-style-type: none"> ○ <i>Specifications Standards Plan</i> ○ <i>Specifications Delivery Roadmap</i> ○ <i>Standards Analysis Supporting Document</i> 	<ul style="list-style-type: none"> • You now have access to all the documentation required for commencing the CCD process • You may read or download the requirements as required

Step	Stage	Vendor action	Result
2.	Download and review the My Health Record Welcome Pack	<ul style="list-style-type: none"> • Download the welcome pack from the Software Vendor Support page: https://developer.digitalhealth.gov.au/resources/faqs/my-health-record-software-vendor-support-page • Read the welcome pack, which contains: <ul style="list-style-type: none"> ○ <i>Guide to the My Health Record system connection process (this document)</i> ○ <i>Software vendor product details form</i> ○ <i>Conformance vendor declaration form</i> ○ <i>Instructions for completing the conformance declaration form</i> ○ <i>My Health Record system vendor contacts list</i> 	<ul style="list-style-type: none"> • You have an overview of the stages required to gain software connection to the My Health Record system
3.	Apply for access to the HI Service Note: This step does not apply to CIS software connecting via the B2B CIS to NPP Service	<ul style="list-style-type: none"> • If not previously registered with the HI Service, apply for access directly through the HI website: https://www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/healthcare-identifiers-service-software-developers 	<ul style="list-style-type: none"> • HI Service access granted

Step	Stage	Vendor action	Result
4.	Complete product details and NASH forms	<ul style="list-style-type: none"> • Complete the following forms: <ul style="list-style-type: none"> ○ <i>Vendor Product Details Form (contained in the welcome pack)</i> ○ <i>Application to Request a NASH PKI test certificate kit form</i> • Return the forms to OTS at: otsliaison@servicesaustralia.gov.au 	<ul style="list-style-type: none"> • OTS issues the NASH PKI test certificate kit • The National Infrastructure Operator (NIO) selects the appropriate test cases based on the product details supplied • Access to the SVT environment
5.	Have your test provider's HPI-I linked to your test organisation's HPI-O	<ul style="list-style-type: none"> • Contact OTS at: otsliaison@servicesaustralia.gov.au and ask to have your test provider's HPI-I linked to your test organisation's HPI-O <p>Note: OTS require both the HPI-I and HPI-O numbers.</p>	<ul style="list-style-type: none"> • Test HPI-I and HPI-O linked
6.	Commence software product development / enhancement	<ul style="list-style-type: none"> • Develop software product based on technical specifications obtained through the Agency website 	<ul style="list-style-type: none"> • Product is developed / enhanced to include My Health Record functions • System Operator provides technical support for software design, development and testing • You may contact the System Operator via email or phone for assistance with this process: email: help@digitalhealth.gov.au phone: 1300 901 001

Step	Stage	Vendor action	Result
7.	Receive NASH PKI test certificate kit and NOC test pack	<ul style="list-style-type: none"> • Receive the NASH PKI test certificate Kit • Receive the established NOC test cases and test data for the My Health Record functions included in your software from the OTS team • Obtain relevant CCD testing materials and instructions from the System Operator at: https://www.digitalhealth.gov.au/ • Make arrangements to conduct formal NOC testing with NIO by emailing: MyHealthRecord.SVT@accenture.com 	<ul style="list-style-type: none"> • Test certificates allow NOC and conformance testing within SVT • Conformance testing may begin • NOC testing may begin • NIO will provide technical support for NOC testing
8.	In-house conformance testing	<ul style="list-style-type: none"> • Conduct in-house conformance testing based on: <ul style="list-style-type: none"> ○ the conformance profiles and the specifications they reference; and ○ the conformance requirements for software products connecting to the My Health Record system • It is recommended that you: <ul style="list-style-type: none"> ○ utilise conformance test specifications; and/or ○ use the Clinical Package Validator test tool. • Retain a copy of all conformance testing results 	<ul style="list-style-type: none"> • Vendor has a history of successfully completed test cases and results <p>Note: The System Operator may wish to view these results as part of quality assurance activities that may be undertaken in the future.</p>

Step	Stage	Vendor action	Result
9.	Formal NOC testing	<ul style="list-style-type: none"> Conduct formal NOC testing observed by NIO. 	<ul style="list-style-type: none"> NIO observe the formal testing and extracts log files and screen shots for verification of test case results When NOC testing is successful, you will receive a copy of the <i>Declaration of Notice of Connection form</i>
10.	<i>Conformance Vendor Declaration Form</i>	<ul style="list-style-type: none"> Complete the <i>Conformance Vendor Declaration Form</i> Email the form to the System Operator at: myhealthrecord.operations@digitalhealth.gov.au 	<ul style="list-style-type: none"> You declare that your software product complies with all applicable My Health Record technical specifications and conformance points and has undergone the necessary internal testing
11.	My Health Record production system access	<ul style="list-style-type: none"> If requested, supply test evidence to the System Operator Receive the production access letter 	<ul style="list-style-type: none"> System Operator completes technical changes to enable your software to access the My Health Record system Healthcare providers may now use your software to access the My Health Record system Your software product is added to the Digital Health register of conformant software

5 Support contacts

5.1 Registration

If you require assistance with the process of registration for My Health Record testing, please contact OTS on:

Email: otsliaison@servicesaustralia.gov.au

Phone: 1300 550 115

5.2 Development

If you require assistance with developing your software for conformance testing, please contact the System Operator:

Email: help@digitalhealth.gov.au

Phone: 1300 901 001

5.3 Testing and non-urgent production issues

If you require technical assistance during the testing phase or you have production issues, please contact OTS:

Email: myhealthrecord.otshelpdesk@servicesaustralia.gov.au

Phone: 1300 550 115

5.4 Production Issues

Report functional or system availability issues via the following contacts:

- **Business Hours:** OTS - 1300 550 115 or otsliaison@servicesaustralia.gov.au
- **After Hours:** My Health Record Incident Support - 1800 723 471 (select option 2)

Definitions

Term	Description
Access Channel	Services in My Health Record system that enable users to access My Health Record. Examples include: Provider (<i>National Provider Portal</i>) and CIS (<i>B2B Gateway</i> and <i>B2B CIS to NPP Service</i>).
B2B	Business-to-Business
B2B CIS to NPP Service	An access channel which enables clinical information systems and healthcare providers to authenticate, authorise and gain access to a patient's My Health Record via the National Provider Portal.
B2B Gateway	An access channel by which external systems, such as clinical information systems and registered repositories, interact with the My Health Record system.
CCD	Conformance, Compliance and Declaration
CIS	Clinical Information System
CSP	Contracted Service Provider (under Section 5, My Health Record Act 2012). An entity contracted to a healthcare provider organisation to provide: <ul style="list-style-type: none"> information technology services relating to the My Health Record system; or health information management services relating to the My Health Record system
Declaration	Statement from the vendor declaring required information and conformance to requirements
HI	Healthcare Identifiers
HPI-I	Healthcare Provider Identifier–Individual (HPI-I)—allocated to individual healthcare providers (for example general practitioners) involved in providing patient care.
HPI-O	Healthcare Provider Identifier–Organisation (HPI-O)—allocated to healthcare organisations (for example a hospital or medical clinic) where healthcare is provided.
My Health Record	Formerly known as the Personally Controlled Electronic Health Record (PCEHR)
NASH	National Authentication Service for Health
NIO	National Infrastructure Operator
NOC	Notice of Connection
NPDR	National Prescription and Dispense Repository (decommissioned December 2016)
NPP	National Provider Portal. A web portal that allows provider-only access to view a consumer's My Health Record.

Term	Description
OTS	Online Technical Support. Vendor support helpdesk operated by Services Australia for HI and vendor support services.
PCEHR	Personally Controlled Electronic Health Record (renamed to My Health Record)
PKI	Public Key Infrastructure
SVT	Software Vendor Test. A pre-production environment for testing software that will connect to the My Health Record System.
System Operator	The System Operator is presently the Australian Digital Health Agency. It is responsible for establishing and operating the My Health Record system.